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No. EL895072126US

Patent Application

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. of:	Jonathan S. Stinson, et al.	Art Group: 2165
Serial No.:	08/905,821 (Prior Appl.)	Examiner: Michael J. Milano (Prior Appl.)
Serial No.:	(New Appl.)	Atty. Docket: 23,369-134
Filed:		
For:	Radiopaque Markers for Implantable Prostheses	

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Before considering this application on the merits, please amend this application as follows:

In the Specification:

Page 1, lines 1 and 2, delete "RADIOPAQUE MARKERS AND METHODS OF USING THE SAME" and insert -- RADIOPAQUE MARKERS FOR IMPLANTABLE PROSTHESES --.

Page 1, immediately after line 2, insert the following paragraph:

--This is a divisional of copending prior application Serial No. 08/905,821, filed August 1, 1997. --.

Replace Table 1 at page 5 with the following table:

Element or Material	Atomic Number or Effective Atomic Number	Linear Attenuation Coefficient at 50 KeV, cm^{-1}
hydrogen	1	.000028
carbon	6	.417
fat	6.46	.193
water	7.51	.2245
muscle	7.64	.233
air	7.78	.000247
nitrogen	7	.000228
oxygen	8	.000280
bone	12.31	.573
titanium	22	5.46
iron	26	15.42
cobalt	27	18.94
bromine	35	13.29
zirconium	40	40.04
iodine	53	60.76
barium	56	49.68
tantalum	73	94.95
platinum	78	149.08
gold	79	140.12
lead	82	91.17
bismuth	83	82.12
iridium	77	151.53
nickel	28	21.98

Page 5, line 17, change "10" to --5.46-- and "120" to --151.53--.

Page 6, line 10, change "30" to --about 49.68-- and "120" to --149.08--.

Page 6, line 21, change "10" to --5.46--.

Page 6, line 22, change "120" to --151.53--.

Page 6, line 30, change "10" to --5.46-- and "120" to --151.53--.

Page 7, line 22, change "10" to --5.46-- and "120" to --151.53--.

Page 7, line 31, change "10" to --5.46-- and "120" to --151.53--.

Page 8, line 20, change "10" to --5.46--.

Page 8, line 21, change "120" to --151.53--.

Page 8, line 28, change "10" to --5.46--.

Page 8, line 29, change "120" to --151.53--.

Page 9, line 7, change "10" to --5.46-- and "120" to --151.53--.

Page 15, line 1, change "10" to --5.46--.

Page 15, line 2, change "120" to --151.53--.

Page 15, line 12, change "10" to --5.46-- and "120" to --151.53--.

Page 15, line 24, change "10" to --5.46-- and "120" to --149.08--.

Page 16, line 3, change "10" to --5.46--.

Page 16, line 4, change "120" to --149.08--.

Page 16, line 16, change "10" to --5.46--.

Page 16, line 17, change "120" to --149.08--.

Page 16, line 29, change "10" to --5.46-- and "120" to --149.08--.

Page 17, line 7, change "10" to --5.46-- and "120" to --149.08--.

Page 17, line 20, change "10" to --5.46--.

Page 17, line 21, change "120" to --149.08--.

Page 18, line 2, change "10" to --5.46-- and "120" to --149.08--.

Page 21, line 8, change "10" to --5.46--.

Page 21, line 9, change "120" to --151.53--.

Page 23, line 9, delete "Application" and insert --No. 6,174,330 --;

Page 23, line 10, delete "Serial No. _____, filed concurrently herewith, and commonly".

Page 23, line 13, delete "Application" and insert --No. 5,980,564 --.

Page 23, line 15, delete "Serial No. _____, filed concurrently herewith and commonly".

Page 23, line 19, delete "Serial No. _____" and insert --Serial No. 08/904,467 --.

Page 29, lines 1 and 2, delete RADIOPAQUE MARKERS AND METHODS OF USING THE SAME" and insert -- RADIOPAQUE MARKERS FOR IMPLANTABLE PROSTHESES --.

In the Claims:

Cancel claim 1, without prejudice.

To confirm an instruction in the accompanying Request for Divisional Application, cancel claims 2-34, without prejudice.

Add the Following Claims:

35. An implantable endoprosthesis and radiopaque marker system including:

an implantable endoprosthesis adapted to be disposed in a body lumen; and

marker having at least one radiopaque portion including a radiopaque material, wherein the marker is removably attached to the implantable endoprosthesis and is removable from the prosthesis when the endoprosthesis is *in vivo*.

36. The system of claim 35 wherein:

the marker has a portion extending away from the endoprosthesis when the marker is so attached thereto, and the marker is removable from the endoprosthesis by pulling said portion away from the endoprosthesis.

37. The system of claim 36 wherein:

the marker is elongate, and said portion of the marker comprises a free end thereof.

38. The system of claim 37 further including:

a component at the free end of the marker for facilitating the pulling of the free end away from the endoprosthesis.

39. The system of claim 38 wherein:

said component is selected from the group consisting of: hooks, knobs, rings, and eyelets.

40. The system of claim 35 wherein:

the radiopaque material includes an element having an atomic number of at least 22.

41. The system of claim 40 wherein:

the radiopaque material includes said element in a form selected from the group consisting of: a metal, a metallic alloy including the element, an oxide including the element, and a salt including the element.

42. The system of claim 40 wherein:

the marker includes a polymer matrix combined with a powder, and the powder includes the element.

43. The system of claim 35 wherein:

the radiopaque portion of the marker is provided as a coating.

44. The system of claim 35 further including:

a delivery device adapted for a delivery of the endoprosthesis to a body lumen and a withdrawal of the delivery device from the body lumen after an implantation of the endoprosthesis within the body lumen; and

wherein the marker is attached to the delivery device whereby said withdrawal of the delivery device removes the marker from the endoprosthesis.

45. The system of claim 35 wherein:

a portion of the marker is woven into the endoprosthesis.

46. The system of claim 35 wherein:

the marker is formed as a spring, and when so attached is retained with respect to the endoprosthesis by a spring force.

47. The system of claim 35 further including:

an adhesive for temporarily securing the marker to the endoprosthesis.

48. The system of claim 35 further including:

a wire for removably attaching the marker to the endoprosthesis.

49. The system of claim 48 wherein:

the wire is engaged with the endoprosthesis and the marker in a manner that requires a removal of the wire from the endoprosthesis before removal of the marker from the endoprosthesis.

50. The system of claim 35 wherein:

the radiopaque material is adapted to be at least partially dispersed from the marker into the body when the endoprosthesis is *in vivo*.

51. The system of claim 35 wherein:

the marker includes a material selected from the group consisting of: barium sulfate, bismuth trioxide, iodine, iodide, titanium oxide, zirconium oxide, gold, platinum, silver, tantalum, niobium, stainless steel, and combinations thereof.

52. The system of claim 35 wherein:

the marker includes at least one hollow or porous portion therein adapted to receive the radiopaque material.

53. A temporary radiopaque marker comprising:

an elongate strand having a proximal end, a distal end, an average thickness of from about 20 microns to about 500 microns, wherein the strand is adapted to be removably attached to an implantable endoprosthesis in a manner that facilitates a removal of the strand from the endoprosthesis by pulling the strand by said proximal end away from the endoprosthesis, and wherein the elongate strand has at least one radiopaque portion including a radiopaque material adapted to be disposed proximate the endoprosthesis when the marker is so attached thereto.

54. The marker of claim 53 wherein:

the proximal end of the strand comprises a component to facilitate said pulling of the strand.

55. The marker of claim 54 wherein:

said component is selected from the group consisting of: hooks, knobs, rings, and eyelets.

56. A process for modifying an implantable endoprosthesis to temporarily enhance a fluoroscopic visualization of the endoprosthesis during and after an implantation thereof in a body lumen, including:

providing a body implantable endoprosthesis;

providing a marker having at least one radiopaque portion including a radiopaque material; and

prior to a deployment of the endoprosthesis in a body lumen, attaching the marker to the implantable endoprosthesis in a manner that facilitates a removal of the marker from the endoprosthesis when the endoprosthesis is *in vivo* after the deployment.

57. The process of claim 56 wherein:

said marker when so attached has a free end extending away from the endoprosthesis, whereby the marker is removable from the endoprosthesis by pulling the free end away from the endoprosthesis.

58. The process of claim 56 wherein:

the attaching of the marker to the endoprosthesis comprises using a mode of attachment selected from the group consisting of: weaving the marker into the endoprosthesis; providing the marker as a spring having a spring force and using the spring force to retain the marker attached to the endoprosthesis; and applying the marker to the endoprosthesis using an adhesive.

59. The process of claim 56 further including:

after attaching the marker to the endoprosthesis, mounting the endoprosthesis releasably to a delivery device.

60. The process of claim 59 further including:

securing the marker to the delivery device, thereby to enable a removal of the marker from the endoprosthesis by withdrawing the delivery device from the lumen after the deployment and with the endoprosthesis remaining in the lumen.

61. A process for deploying an endoprosthesis within a body lumen, including:

providing an elongate marker having at least one radiopaque portion including a radiopaque material;

removably attaching the elongate marker to an implantable endoprosthesis;

placing the endoprosthesis and the attached marker within a body lumen and the endoprosthesis and marker toward a selected site for a deployment of the endoprosthesis and marker in the lumen, while determining a position of the endoprosthesis and marker at least in part by fluoroscopically imaging the marker; and

after deploying the endoprosthesis and marker at the selected site, removing the marker to leave the endoprosthesis at the site.

62. The process of claim 61 further including:

prior to placing the endoprosthesis and marker within the body lumen, loading the endoprosthesis and marker into a delivery device, and using the delivery device to move the endoprosthesis and marker toward the selected site; and

wherein deploying the endoprosthesis and marker comprises releasing the endoprosthesis and marker from the delivery device.

63. The process of claim 62 further including:

attaching the elongate marker to the delivery device before using the device to move the marker and endoprosthesis toward the selected site;

wherein said removing the marker consists essentially of withdrawing the delivery device from the body lumen after releasing the endoprosthesis and marker.

REMARKS

The foregoing amendment to the specification is consistent with an earlier amendment to prior application Serial No. 08/905,821 with issued patent numbers provided when available. The applicant respectfully requests entry of the amendment and consideration of claims 35-63 on the merits.

Respectfully submitted,

Boston Scientific Scimed, Inc.

Dated: November 13, 2001

By: ______________________

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CERTIFICATE OF EXPRESS MAILING

Pursuant to 37 CFR 1.10, I hereby certify that this Preliminary Amendment in a Divisional Application based on Application Serial No. 08/905,821 is being deposited with the U.S. Postal Service by Express Mail, Post Office to Addressee service, addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date of deposit and under the mailing label number indicated below.

Date of Deposit: November 13, 2001

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Geralyn M. Vita

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